DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Microbiology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Microbiology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 8, 2000, 9:30 a.m. to 4:30 p.m.

Location: Marriott Washingtonian Center, Salons A, B, C, and D, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact Person: Freddie M. Poole, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–2096, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12517. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss and make recommendations on issues concerning the types of information necessary to determine the effectiveness of in vitro diagnostic devices that detect human papilloma virus (HPV) in women 30 years or older when these devices are used: (1) In conjunction with Pap smear to increase the effectiveness of Pap smear screening for cervical cancer, and (2) without Pap smear to determine a woman's risk of cervical cancer. Additionally,

the committee will discuss and make recommendations on issues concerning the use of self-collection and alternative specimen sources for the above indications.

The following draft questions are proposed for discussion and may be subject to changes prior to the committee meeting:

1. What criteria should be developed to support the safety and effectiveness of HPV assays used in conjunction with Pap smears and without Pap smears, in women 30 years or older, for predicting risk for cervical cancer?

2. What would be the appropriate interpretation of results from HPV assays used in conjunction with Pap smear in women 30 years or older intended for use as predictors of risk for cervical cancer?

3. What type(s) of clinical studies would be appropriate to establish the safety and effectiveness of human papilloma virus testing used in conjunction with Pap smear and without Pap smear, in women 30 years or older, for the determination of risk for cervical cancer in the U.S. population?

4. What types of studies would be appropriate to establish performance characteristics for alternate specimen sources, e.g., urine or home collected cervical swabs, when used to test for HPV as an indication of risk for cervical cancer?

FDA will consider these recommendations in the future development of review criteria for in vitro diagnostic devices, for the detection of HPV as valid scientific evidence to determine whether there is reasonable assurance that these devices are safe and effective for their intended uses.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by December 1, 2000. On December 8, 2000, oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m., and between approximately 3:30 p.m. and 4 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral

presentations should notify the contact person before December 1, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

FDA regrets that it was unable to publish this notice 15 days prior to the December 8, 2000, Microbiology Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring this issues to public discussion and qualified members of the Microbiology Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: 11/22/00
November 22, 2000.

Linda A. Suydam
Linda A. Suydam,
Senior Associate Commissioner.

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